NDA 20-201/S-009 & S-012 **SEP 1 1999**

Abbott Laboratories
Attention: Ms. Leslie Koehler
D-389, Building AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Dear Ms. Koehler:

Please refer to your supplemental new drug applications dated February 16, 1996 (S-009), received February 20, 1996 and July 24, 1998 (S-012), received July 31, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dobutamine in 5% Dextrose Injection in Flexible Containers.

We acknowledge receipt of your submission dated June 25, 1999.

Your submission of June 25, 1999 constituted a complete response of our March 26, 1999 approvable letter to S-012.

NDA 20-201/S-012 provides for final printed labeling as follows:

1) Under **INDICATIONS AND USAGE**, "adults with" in the third line, first paragraph, has been deleted.

2) Under **PRECAUTIONS**, a **Geriatric Use** subsection has been added beneath the Pediatric Use subsection. It reads as follows:

   Clinical studies of Dobutamine did not include sufficient numbers of subjects aged 65 and over being treated for acute cardiac decompensation to determine whether they respond differently form younger subjects. Other reported clinical experience suggests that the incidence of significant hypotension is a function of both dose and age, older individuals having a greater incidence of hypotension. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

3) Under **PRECAUTIONS**, the **Drug Interactions** subsection (in its entirety) has been moved from underneath the **Pediatric Use** subsection to immediately beneath the **Usage Following Acute Myocardial Infarction** subsection.

4) The symbol "**:g**" was replaced throughout the package insert with "**mcg**" when appropriate.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted June 30, 1999). Accordingly, this supplemental application (S-012) is approved effective on the date of this letter.

In addition, we have reviewed the labeling that you submitted in accordance with our February 17, 1999 approval letter for NDA 20-201/S-009, and we find it acceptable.

We have noted that, at the present time, you have decided not to market Dobutamine in Dextrose 5% Injection in Larger Volume Glass Containers (NDA 20-269, S-006 and S-007). Please submit final printed labeling (FPL) for these supplements when you decide to market them.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Edward Fromm
Consumer Safety Officer
301-594-5313

Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research